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A biomechanical comparison of distal radius fracture stability using different external fixators

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A Biomechanical Comparison of Distal Radius Fracture Stability Using Different External Fixators

A thesis submitted to the Yale University School of Medicine in partial fulfillment of the requirements for the degree of Doctor of Medicine

Gregory L. Austin

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A Biomechanical Comparison of Distal Radius Fracture Stability Using Different External Fixators. Gregory L. Austin, Scott W. Wolfe. Department of Orthopaedics and Rehabilitation, Yale University, School of Medicine, New Haven, CT.

Simulated unstable extra-articular distal radius fractures were created in seven fresh, frozen cadaveric upper extremities and stabilized using four different external fixators, the Orthologic, EBI, AO, and Orthofix frames. Physiologic muscle tension across the wrist was simulated by application of a 40N load distributed among the wrist tendons. Alternating loads of up to 100N in flexion and extension of the wrist were applied during stability testing, and the kinematics of the proximal and distal fracture fragments determined using attached infrared light-emitting diodes and a three-dimensional motion tracking system. Fracture stability was reassessed for each of the constructs after augmentation of the fracture fragments with a single dorsal transfixion K-wire. Motion was measured in the flexion/extension plane, in the plane of radial/ulnar deviation, and in the plane of rotational motion. K-wire augmentation demonstrated a reduction in motion of the distal radial fragment of at least 40 percent in all three planes. For flexion/extension, the reduction in motion was from 4.5° to 2.6°. For radial/ulnar deviation, the range of motion decreased from 3.0° to 1.5° with the addition of the transfixion k-wire. Rotational motion declined from an average of 3.2° to 1.8°. Addition of the single dorsal transfixion k-wire significantly improved stability of each of the four fixators in at least one of the three planes in which motion was measured. The data generally do not support any real differences among the four fixators, although there is evidence that the EBI may be less stable than the Orthofix. The data more strongly support the concept of k-wire augmentation for increasing stability of

an unstable extra-articular distal radius fracture regardless of the external fixator that is utilized.

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INTRODUCTION

Distal Radius Fractures

Distal radius fractures are one of the most common injuries in orthopaedics. Distal radius fractures represent a large array of clinically distinct entities. Typically, younger individuals sustain these injuries through high-energy collisions, often through motor vehicular accidents or athletic events. Older individuals are more likely to suffer fractures of the distal radius through a simple fall. In almost all cases, the most important mechanism is axial compression of the distal radius by the carpal bones. This generally occurs as the patient falls on an outstretched hand. Because of the heterogeneity of these injuries, a system was necessary to help classify these injuries and guide treatment. In 1967, Frykman developed a classification for fractures of the distal radius that has helped guide treatment decisions for the surgeon, and this is presented below.[1]

Frykman Classification of Colles' Fractures		
	Distal Ulnar Fracture	
Fracture	Absent	Present
Extra-articular	I	II
Intra-articular involving radiocarpal joint	III	IV
Intra-articular involving distal radioulnar joint	V	VI
Intra-articular involving both radiocarpal and distal radioulnar joint	VII	VIII

Although a Colles' fracture had typically been described as an extra-articular fracture, Frykman's classification allowed for a broader and more meaningful system by which to classify and treat most fractures of the distal radius.

Complications of Distal Radius Fractures

In addition to being one of the most common injuries seen in orthopaedics, fractures of the distal radius have also proven to be one of the most difficult to treat. This difficulty arises in part from the heterogeneous nature of the injuries, but is also related to the difficulty in regaining anatomic and functional normalcy following the injury. The consequences of an inadequately treated distal radius fracture can be devastating. Several authors have noted that malunion following treatment of a distal radius fracture results in physical deformity, weakness, stiffness, and frequent pain of the wrist.[1,2,3] A correlation has been made to the severity of the initial injury and both anatomic and functional outcomes. It has been shown that those with extensive comminution and intra-articular involvement with associated soft tissue injury are at risk for having a poorer outcome than those who sustain fractures of the distal radius without these characteristics.[1] Technique for the treatment of these injuries is open to debate, but is directed at attaining the best anatomic and functional outcome while minimizing complications.[4,5]

Treatment Options for Distal Radius Fractures

Treatment decisions for distal radius fractures are guided by an assessment of the stability of the fracture. Several criteria are used to assess stability, although many authors have used different cutoffs. One of the criteria used by the surgeon is the degree of initial fracture displacement. While there is no consensus on the exact cutoff level, some have suggested that a fracture with dorsal angulation of greater than 20 degrees represents an unstable fracture. Additionally, fractures with significant dorsal comminution and those with shortening of the radius of approximately 10

mm or more are also considered unstable.[6] Initial displacement, degree of dorsal comminution, and radial shortening are initial criteria for classification for an unstable fracture. Fractures that are considered stable are generally extra-articular and only have moderate displacement. They usually do not redisplace to the original deformity when reduced, and they are generally treated with closed reduction and cast immobilization for three to six weeks. Several different casts and splints are available and choice is left to the preference of the surgeon. However, this method of treatment sometimes fails to maintain reduction of the fracture and may result in a residual dorsal angulation of 10 degrees or more or unacceptable radial shortening. This fracture is secondarily classified as unstable.[7] In addition to the extensive comminution and radial shortening, unstable fractures often have articular fractures that involve both the radiocarpal joint and the distal radio-ulnar joint (DRUJ). The fractures lead to more complications, such as loss of reduction, carpal tunnel syndrome, and instability of the DRUJ.[1] Because of these complications, unstable intra-articular fractures of the distal radius may require different methods of treatment.

Closed reduction with subsequent cast immobilization is one option for treatment of unstable distal radius fractures. If closed reduction is unsuccessful, open reduction with cast immobilization can be attempted. Both of these methods may fail to maintain adequate alignment over time.[4,5] Another option is open reduction with internal fixation. However, results with this technique have been equivocal because it is technically difficult. Additionally, internal fixation is associated with several complications, such as tendon adhesion, painful hardware, and loss of reduction. Up to 35% of patients treated with internal fixation require further surgical procedures.[8]

Because of the equivocal or unsatisfactory results of other methods, percutaneous fixation of unstable fractures of the distal radius has become a mainstay in treatment of these injuries.

External Fixation of Distal Radius Fractures

Despite the skillful use of closed or open methods, some fractures are inherently unstable and treatment requires immobilization through the use of sustained traction, known as external fixation. External fixators usually involve the insertion of two sets of parallel pins, one set generally placed into the second (and/or third) metacarpal and the other set inserted into the radius, proximal to the fracture site. Frykman Type VII and VIII fractures typically require external fixation, but other fractures, particularly intra-articular fractures with a high degree of comminution may also benefit from the application of an external fixation device. An important concept in the use of external fixation is ligamentotaxis. This concept has been described by Vidal and others as a way of maintaining reduction of the fracture by applying distraction across the wrist to achieve and maintain fragment alignment through soft-tissue tension.[9] Vidal was able to demonstrate that ligamentotaxis allowed restoration of the radial length as well as the postreduction position of the bony fragments of the distal radius. Several authors have investigated the use of external fixation in small clinical studies using one or more of the commercially available devices.

Horesh et al conducted a prospective study to evaluate the outcomes of 40 young, active adults who were treated with closed reduction and application of the small AO fixator and followed for an average of 36 months.[10] Using subjective criteria[3,11] (e.g., pain, feeling of weakness, or

restriction of activity), they found that 35 patients had a good or excellent outcome, with four having a fair outcome and one having a poor outcome. They also assessed their subjects using objective criteria (e.g., measured range of motion, measured grip strength, or residual anatomic deformity) and found that 36 had good or excellent outcomes, with four having a fair outcome and none having a poor outcome. The authors did not indicate whether the four patients with an objectively fair outcome were among the five patients who did not have a good or excellent subjective outcome. Unlike other studies, this study reported few complications, especially concerning pin infections. One case of reflex sympathetic dystrophy (RSD) occurred which required a long period of physiotherapy. The only other complication in this series was one case of carpal tunnel syndrome (CTS) that developed within three months of external fixation. This resolved upon surgical decompression. This study did not employ a control group to compare the outcomes to those who were treated with external fixation devices.

Leung et al also conducted a prospective study with an average follow-up of eleven months for 72 consecutive comminuted distal radius fractures, with over 90% being intra-articular and 47% being of Type VII and VIII, according to the Frykman classification.[12] This study used a combination of external fixation, with the Hoffman device, and bone grafting for treatment. They found that 80% of the patients regained full ROM in the hands, wrists, and forearms and that they also had strong and pain-free wrist function. Radiographic evidence after reduction showed nearly normal angles of volar tilt had been achieved, and this was maintained in all but three patients. They did, however, find that there were always mild losses in the angle of

radial articulation averaging 2.2 degrees. Their study was not without complications. One patient developed a fracture of the index metacarpal as the 3 mm half-pin (for the external fixator) was too large for the relatively thin metacarpal shaft. This fracture healed uneventfully. One patient developed a neuroma of the superficial sensory branch of the radial nerve with significant hyperaesthesia and three others developed similar but milder symptoms. Fortunately, all recovered fully and spontaneously. Two patients developed CTS which was only transient. Two patients did develop RSD which required long-term physical therapy, but eventually resolved completely. They concluded that ligamentotaxis and bone grafting produced excellent results. This study also did not include a control group.

Suso et al performed a prospective, follow-up study (average follow-up of 38 months) of 28 patients with fractures of the distal radius using the medium-sized Hoffman fixator.[13] Twenty-four of the 28 patients had sustained a fracture of Type VII or VIII, according to the Frykman classification. Using the system based on the work by Gartland and Werley,[3] they found that 23 of their 28 (82%) patients had good or excellent outcomes, while 3 had a fair outcome and two patients had a poor outcome. Objectively, six of the 28 patients were found to have residual deformity and had partial loss of reduction. They found that radial and ulnar inclination was decreased in half the patients. Radial inclination was decreased to a somewhat greater degree, which the authors postulated was the result of the fractures being immobilized in ulnar deviation. In no patient was range of motion in the flexion/extension plane limited by more than 20 degrees. Only three of the 28 patients had a measured loss of the arc of mobility of more than 50%. Two additional patients had loss of the arc of mobility of between 25-50%.

Interestingly, the authors noted that 19 of the 20 patients who were under the age of 40 had good or excellent results. Conversely, this means that only four out of the eight patients over the age of 40 had a good or excellent outcome. The sample sizes were obviously too small to make meaningful statistical comparisons, but the authors felt this trend might be clinically significant. Unfortunately, they did not comment on reasons why patients over 40 seemed to have a trend towards a poorer outcome. This study reported few complications, including only four cases of minimal but painless signs of degenerative arthritis. The authors also found a correlation between anatomic and functional outcome, and concluded that their results were good enough to justify the use of external fixation with the goal of producing better anatomic results. They also felt that external fixation had a clear advantage in that it allowed access for caring for the wound, particularly important for open fractures. This study's yield of 82% of patients with a good or excellent result is in line with that of the other authors, but again no control group was used.

Vaughan et al performed a prospective follow-up study (average follow-up of 58 months) in 52 patients using the Roger Anderson fixator.[6] This study included 30 patients who had immediate (within 24 hours of injury) application of an external fixator and 22 patients who had delayed fixation (average delay was 11 days). They used similar criteria for application of the external fixator: intra-articular involvement, radial shortening of 10 mm or more, dorsal angulation of 20 degrees or more, severe dorsal comminution, or failure of closed reduction and casting. Using the Sarmiento demerit point-rating system,[11] 15 patients had an excellent outcome, 31 had a good result, while only 6 had a fair outcome with none

having a poor outcome. Five patients, all of whom had severe continuous wrist pain, were subjectively dissatisfied with their outcome, but their objective criteria placed them in the fair category according to the Sarmiento system. In these patients treated with the Anderson fixator, 7 of the 52 patients developed complications. Two patients had irritation of the dorsal sensory branch of the radial nerve, one of whom had spontaneous resolution while the other continued to have paraesthesia over the dorsum of the thumb. There was one uncomplicated episode of a pin tract infection, one case of pin loosening requiring removal of the fixator, and two cases where a pin broke in the medullary canal of the radius during insertion, although there were no long-term adverse consequences. One year after application of the fixator, one patient had a secondary non-displaced fracture of the radius at the site of a radial pin. The authors did note that of the 25 patients in the study over the age of 60, only one patient had an occurrence of pin loosening. They argued that this did not support the assertion by Grana and Kopta[14] that the external fixator should be reserved only for younger patients with strong, bony cortices.

In one of the few randomized studies, Roumen et al reported on 101 patients over the age of 55 (mean age of 70 yo).[7] Initially, all patients were treated within six hours of the injury with closed reduction and cast immobilization. These patients were reviewed on day one, day seven, and day fourteen. Subsequently, 43 patients had either 5 mm or more of radial shortening or more than 10 degrees of dorsal angulation after initial reduction. Of these 43, 21 individuals were randomly assigned to receive treatment with an Ace Colles fixator, and 22 patients were assigned into a control group where the conservative treatment of cast immobilization was

continued. Interestingly, the authors found that the patients treated with external fixation had a good anatomical result, but their function was not any better than that of the control group. The anatomic results of the 21 patients treated with an external fixator produced 16 with a good or excellent result, four with a fair result, and one with a poor result. By definition, none of those in the control group could be classified as having a good or excellent anatomic result. Thirteen were classified as fair and nine poor. However, when comparing functional outcomes, only 12 of 21 patients treated with an external fixator showed a good or excellent outcome, while five were fair and four poor. Surprisingly, 19 of the 22 patients in the control group had a good or excellent functional outcome, with only one having a fair result and two having a poor outcome. Of note, 44 of the 58 patients that did not sustain secondary displacement of their fracture had a good or excellent anatomic outcome, with six having a poor outcome. Also, 41 of the 58 had a good or excellent functional outcome, with only three having a poor result.

Roumen et al did not find a correlation between final anatomical and functional outcome. In patients over 55 yo, they concluded that the severity of the original soft-tissue injury was the major determinant of functional results. They recommended conservative management of unstable distal radius fractures in patients over the age of 55. The authors noted while many authors have found a direct correlation between anatomic and functional outcomes,[1,17,18,19] other authors have not been able to substantiate these results.[20,21] They further argued that many of the studies on external fixators, such as the ones previously discussed here, do not have a control group.

There is some supporting evidence in the literature for the assertions made by Roumen and his group. McQueen et al showed remanipulation and plaster after secondary displacement of a distal radius fracture did not benefit patients over the age of 60.[22] The patient population studied by Roumen not only did not show a correlation between anatomic and functional outcome, their complications were greater and seemed to be more severe than those encountered in the previously described studies. Of the 101 patients, 14 developed RSD, which was severe enough in five patients to produce a very poor functional outcome. The other nine cases of RSD resulted in morbidity sufficient to lead to only a fair outcome. The authors found no correlation between the development of RSD and the anatomical result. An additional twelve patients in the study developed CTS, confirmed by EMG. There was no overlap between those who developed CTS and those who developed RSD. Twelve patients had sixteen digits with stenosing tenosynovitis requiring operative release. At six months, 36% of patients had some persisting pain. Overall, older patients seemed to have a poorer overall outcome. Only 57% of the patients in this study had a good or excellent outcome compared to the other studies which generally showed good or excellent outcomes in well over 80%.

A prospective follow-up study (average length of follow-up was 42 months) of 132 patients (mean age of 35 yo) with unstable intra-articular fractures treated with the Hoffman fixators was done by Jakim et al.[23] They found a significant correlation between fracture severity and clinical outcome, but found that clinical outcome was not related to radiographic evidence of restoration. Their conclusion that articular and soft-tissue damage are a major determinant of functional outcome lends some support to the study by

Roumen. However, Knirk and Jupiter found that the incidence of osteoarthritis was 91% when articular congruency was not restored, but only 11% when it was restored.[24] Additionally, Bacorn and Kurtzke evaluated over 2000 patients and found a direct correlation between residual anatomic deformity and mean functional disability.[2]

Augmented external fixation

In an attempt to improve the efficacy of external fixation, some authors have promoted the use of augmented external fixator constructs, with the addition of Kirschner wires to provide further stability for unstable fractures of the distal radius.[25,26] Seitz et al performed a prospective follow-up study (mean follow-up of 2.5 years) of 51 patients (mean age of 50 years) with comminuted, unstable intra-articular distal radius fractures treated with external fixation and supplemental 0.062-inch K-wires.[25] The authors had observed that often even well-reduced fractures can undergo late displacement or collapse with resultant loss of the initial articular congruity. The authors postulated that the use of supplemental K-wires would allow for maintenance of articular congruity. They augmented their external fixator constructs with three K-wires. They found that 92% of the patients had a satisfactory restoration of the articular surface. They reported few complications, one case of RSD, two patients with diminished grip strength and ulnar-sided wrist pain, and five patients with uncomplicated episodes of pin tract infections. They also reported that there were no cases where loose pins resulted in loss of fixation. The authors asserted that muscle-tendon units that traverse the wrist can cause a lateral/rotational displacement of the radial styloid fragment as well as impaction of the lunate fossa fragment and that the addition of K-wires allows the external fixation construct to resist

these forces. This increase in efficacy of the fixator construct did not increase the complication rate. The authors proposed the use of the supplemental K-wires as a "joystick" to help restore and maintain articular surface congruency.

While other clinical studies have helped confirm the findings of Seitz, Wolfe et al were the first to biomechanically assess the efficacy of augmented fixation as well as the ideal K-wire construct.[27] They used eight fresh-frozen cadaveric specimens, performed an osteotomy to simulate an unstable extra-articular distal radius fracture, and tested eleven commonly used K-wire constructs. They found significant reductions in the flexion/extension plane with the use of a single styloid or dorsal transfixion K-wire. Overall, the dorsal transfixion construct appeared to offer some increase in fracture fragment stability. The authors concluded that their data supported the concept of augmented external fixation. They further asserted that their results, in combination with the findings in the clinical series, supports the idea of using augmented external fixation to reduce the dependency on ligamentotaxis to maintain fracture stability. Some authors have asserted that ligamentotaxis can lead to excessive distraction across the wrist producing complications such as wrist stiffness and RSD.[28,29] A study by Kaempfe showed outcome was inversely related to the duration and amount of distraction across the wrist.[29] The importance of the increased stability afforded by the addition of supplemental K-wires is supported by the work of Wu et al. They demonstrated that mature bone healing is delayed both biomechanically and histologically as fixator stability decreases.[30]

Clinical Comparisons of external fixators

While many studies have assessed the outcomes using external fixators, few clinical studies have attempted to compare one external fixator against one or more different fixators. No single study has attempted a large, controlled, randomized trial of the various fixators. Such a study is unlikely given the complexity, expense, and constant evolution of the available devices. Of the clinical studies that have been done to compare the different fixators, all suffer from a lack of standardized methodology. Nevertheless, the studies that have been performed do provide some basis for evaluating efficacy and guiding treatment decisions.

Foster and Kopta conducted a retrospective study of 49 patients (mean age of 36.8 yo) with 50 fractures (42 of which were intra-articular) of the distal radius (one patient had bilateral distal radius fractures) comparing the Anderson fixator against the Hoffman C-series device.[31] Follow-up with the available patients occurred an average of 15.9 months following the initial injury. Of the 50 fractures treated, 24 were treated with the Anderson fixator and 26 with the Hoffman fixator. The authors found that neither device proved to be superior to the other although the Hoffman fixator appeared to be more rigid as measured by the degree of radial shortening. All patients had good or excellent results with respect to radial length. Both fixators yielded satisfactory range of motion in the patients. As for volar tilt, 8 of 26 treated with the Hoffman device had a poor outcome, while five of the 24 treated with the Anderson had a poor outcome. The authors did not draw any conclusions concerning the significance of the poor residual volar tilt that was found in 13 of the 50 fractures. The residual dorsal tilt in the thirteen patients did not appear to affect functional outcome, as over 90% of the

patients treated with each fixator were satisfied with their outcome and only one patient had daily wrist pain (Anderson device). Over 90% of patients had achieved good or only slightly decreased strength and had been able to resume all normal activities. Complications in this trial were significant for six pin tract infections, three of which required surgical debridement (all three of these had been treated with the Hoffman device). There was only one case of CTS and no reported cases of RSD.

In another clinical comparison, Cooney performed a clinical trial in which he analyzed four external fixators in a consecutive series of 100 unstable distal radius fractures.[28] The four fixators used were the Roger Anderson (n=60), the Ace-Colles (n=15), the mini-Hoffman (n=15), and the Hoffman C-series (n=10). He found that each of the fixators produced similar levels of good or excellent results with respect to functional outcome, range of motion, and incidence of complications. Overall, 86% of the patients had good or excellent results. Cooney, however, found an unsatisfactory rate of complications. Overall, 34% had at least one complication. Fourteen patients had pin tract infections, four had CTS, five developed upper limb dystrophy, four had arthrofibrosis, four developed post-traumatic arthrosis, and four suffered from loss of fracture reduction. Cooney did not find any difference in the complication rate among the different fixators. He concluded that outcome seems to be independent of the type of external fixator used.

Biomechanical Comparisons of external fixators

While no clinical series has found one fixator that yielded superior results, some biomechanical studies have compared different fixators and have found differences in rigidity. Nakata et al compared the AO against the

mini-Hoffman, the Roger Anderson, and the Ace-Colles by applying each fixator to wooden dowels for biomechanical testing.[19] The authors used the Equivalent Stiffness Index (ESI) to assess the biomechanical rigidity. The AO was calculated to have an ESI almost twice that of all the other devices. The AO was significantly more rigid in the compression mode as well as in the plane of anterior/posterior bending. However, both the mini-Hoffman and the Ace Colles proved to be more rigid than the AO and the Anderson device concerning lateral bending. Unfortunately, this study did not use cadaver forearm specimens for the biomechanical testing. They explained their use of wooden dowels by claiming that because it is a comparison study, the actual material used is irrelevant. Nakata also performed a clinical series in this study by applying the mini-Hoffman fixator to 26 patients. They achieved good functional and anatomic results. They did report three cases where the patient overstressed the system and sustained pin fractures. Because of these pin fractures, the authors supported the used of more rigid fixators in younger, more active individuals.

Frykman et al compared eleven external fixators by applying the fixators to acrylic rods for biomechanical testing.[32] The authors used the ESI to assess the biomechanical rigidity. The authors found that the AO was of intermediate rigidity and that the Orthofix was clearly the most rigid fixator. Additionally, they noted that the AO did not allow for axial compression, while the Orthofix did. On comparison against the Hoffman unilateral fixator, the AO proved to be significantly more rigid in the compression and anterior/posterior bending modes, but was inferior with respect to lateral bending. Additionally, the Hoffman allowed axial compression. The authors had previously asserted that lightweight fixators were more appropriate for

low demand, cooperative, and elderly patients.[19] They believed that a heavier, more rigid fixator (such as the Orthofix) should be reserved for the high demand, more active, younger, and large-boned patient. The authors speculated that an ideal fixator should be adequately rigid to maintain length and reduction while allowing motion at the wrist. Additionally, the fixator should be lightweight, allow versatile pin placement, and be easy to apply. They concluded that none of the eleven fixators met these criteria, and the authors were also unable to determine the ideal rigidity for an external fixator.

Frykman et al conducted a subsequent biomechanical comparison of thirteen fixators four years later and again showed the AO to be of intermediate rigidity with the Orthofix essentially twice as rigid as the others.[33] However, they were again unable to address the ideal rigidity that an external fixator should possess. They did, however, support ideas put forth by Mooney and Claudi,[34] who documented that motion adversely affects osteogenic cells and that initial rigid fixation leads to the best outcome. However, complete stability may lead to a sub-optimal result. Frykman et al concluded that optimal fixation may be a dynamic concept and can change as healing occurs.

Purpose

External fixation has proven to be a reliable technique for comminuted distal radius fractures, with multiple studies reporting restoration of motion and strength approaching 75-80% of the uninjured wrist. Several external fixation designs are available for treatment of distal radius fractures, but there are few biomechanical or clinical studies that compare fracture stability

between fixators. While previous studies have demonstrated wide variations in structural rigidity among different external fixators, the studies were performed on wooden and acrylic dowels and the constructs were not tested under physiologic loads. Some authors have recommended that lightweight fixator designs be reserved for elderly or less active patients, based on the mechanical properties of the fixator and not on the relative stability of the fracture or on the muscle forces realized at the fracture site. Indeed, the biomechanical requirements of external fixation for fractures of the distal radius are not known, and muscular forces across the wrist can only be estimated. The ideal fixation device would maintain the operative reduction until healing by providing the fracture with sufficient stability to overcome physiologic forces, but would allow sufficient load transfer across the fracture site to stimulate healing.

Augmentation of external fixation using percutaneous Kirschner wires has demonstrated clinical success, and has been shown to significantly increase fracture stability when compared to external fixation alone. The relative contributions to stability provided by the supplemental wires and that provided by the biomechanical properties of the fixator itself are not known. We hypothesized that addition of supplemental K-wire fixation was more critical to stability of distal radius fracture fixation than the biomechanical rigidity of the external fixator. The purpose of our study was to compare the *in vitro* fracture stability of several commonly used fixators, with and without supplemental K-wire augmentation.

METHODS

Seven fresh-frozen cadaveric hand-wrist-forearm specimens were used in this study. They were all prepared in the same manner.

Specimen Preparation

The first step in preparation of the specimen was dissection of the forearm. All of the skin and superficial muscles from the forearm and hand were removed. At this point, the five wrist motor tendons [extensor carpi radialis longus (ECRL), extensor carpi radialis brevis (ECRB), extensor carpi ulnaris (ECU), flexor carpi radialis (FCR), and flexor carpi ulnaris (FCU)] were isolated and tagged. Special care was taken to preserve the pronator teres muscle, the wrist capsule and ligaments, the dorsal retinaculum, and the interosseous membrane.

Each wrist motor tendon was then cut to approximately 6 cm from its insertion and secured with a #1 ethicon suture in a long Bunnell fashion. It was necessary to cut the tendons to this length to avoid the tendons getting caught in the pulleys of the flexibility machine on which the biomechanical testing would be performed. The next step was to place a syndesmotic screw across the radius and the ulna at 14 cm from the ulnar styloid. If necessary, the radius and ulna were cut 5 cm proximal to the syndesmotic screw (or 19 cm proximal to the ulnar styloid). This was necessary to standardize the specimens before the specimens were placed in the resin pot for testing.

Application of External Fixator

One of the four external fixators was applied in randomized order to the radial diaphysis and index metacarpal prior to the osteotomy and potting.

Four fixators of widely varying design, weight, and stability were studied: the Orthoframe Mayo fixator (Orthologic Corp., Phoenix, AZ) shown in Figure 1; the AO small double frame fixator (Synthes, Poali, PA) shown in Figure 2; the EBI device (Parsippany, NJ) shown in Figure 3; and the Orthofix Inc. fixator (Richardson, TX) shown in Figure 4. Each of the four external fixators was applied according to its protocol. Each fixator required placement of two metacarpal pins in addition to two pins inserted into the radius. A 3/64 drill bit was used at the pin placement sites. Different drill holes were used for each fixator to avoid loosening during testing. The first pin was placed 5-6 cm from the base of the second metacarpal, just distal to the insertion of the ECRL tendon. The second pin was then placed approximately 2.5 cm from the first pin distally along the metacarpal shaft. In order to place the pins in the distal radius, the external fixator was constructed at 180 degrees (with respect to the radial shaft) and the middle of the fixator was centered over the osteotomy site on the distal radius. The radial pin clusters were placed in order that they would be equidistant from the middle of the fixator in comparison to the metacarpal pins. Special care was taken to align the shaft of the second metacarpal with the shaft of the radius so that both would be parallel to the frame of the external fixator. The fixator was adjusted to maintain neutral tension on the wrist capsule and the wrist ligaments.

Potting of forearm

Four single cortical screws were placed into the proximal radius and ulna, proximal to the syndesmotic screw. This was done to provide better purchase in the mold. The specimen was then secured in a clamp holder and ring stand. Next, the radius was aligned to be vertical in the anterior/posterior and lateral planes using a plumb. The specimen was then

centered in a pot with bolts perpendicular and equidistant to the radial/ulnar plane. Bondo and fiberglass resin were then mixed to the desired consistency. The hardener was then added to the mixture, which was then poured into the pot. The pot was then allowed to dry for one hour. After the mixture had dried, the specimen was then removed and the base was grinded to size to fit into the specimen jig, which was to serve as the platform onto which the specimen would be placed on the flexibility machine for biomechanical testing.

Collection of Pre-Osteotomy Data

The specimen was placed in a jig with three radio-opaque markers labeled as A, B, and C. The fixator was on the opposite side from the ABC markers. The ABC jig with the specimen was then x-rayed. Three infrared light-emitting diodes were attached to the specimen. Each diode was connected to a pin, which was then inserted into the specimen. One diode was inserted into the distal shaft of the second metacarpal. The second diode was placed at the distal end of the radius, distal to the site of osteotomy, which had not yet been performed. The final diode was placed on the distal radial shaft proximal to the osteotomy site. A computer program was used to digitize the x-ray of the specimen and the A, B, and C markers. These same markers were then used as a frame of reference for measuring three-dimensional kinematics of the fracture fragments by the Optotrak device. The Optotrak device used three separately placed lenses to sense the light emitted from the diodes that had been attached to the specimen. At this point, the specimen was ready to undergo the flexion/extension protocol to assess the stability of the distal radius fragment prior to osteotomy. The protocol prior to osteotomy was the same for each specimen and for each

external fixator, with or without the dorsal transfixion k-wire. The flexion/extension protocol was performed as follows.

Specimen Testing: The Flexion/Extension Protocol

The potted specimen was placed into a pneumatic loading device in which loads could be applied to the wrist motor tendons. The sutures that had been attached to the five wrist motor tendons earlier were now attached to pulleys on the machine in preparation for biomechanical testing. The pumps on the pneumatic loading device were calibrated to one, two, and three kilograms comparable to loads one, two, and three. Using the collection algorithm based on the Optotrak system, the neutral position (three-dimensional) of the distal end of the radius was measured and would be used as the point of reference to measure movement in the three directions: flexion/extension, radial/ulnar deviation, and rotational movement. Physiologic muscle tone across the wrist was approximated by applying 9.8 Newtons (N) to each of the four wrist tendon units (FCR, FCU, ECU, and ECRB/ECRL) for a total of 39.2 N across the wrist. Two loading cycles were performed to pre-condition the wrist to control for viscoelastic deformation of the wrist ligaments and capsule, and three-dimensional data were recorded during the third cycle for each experimental configuration. A loading cycle was defined as incremental load increases of 19.6 N, first in extension, then in flexion, to a maximum of 98.1 N of total force across the wrist. During testing, the specimens were kept moist with isotonic saline solution. The wrist joint was loosely wrapped with moist gauze to limit evaporative losses.

Osteotomy

The specimen was removed from the pneumatic loading device in order to perform the osteotomy to simulate a typical extra-articular distal radius fracture. The distal radial diode was removed. The osteotomy was performed 2 cm proximal to the radial styloid. An unstable extra-articular distal radius fracture was simulated by removing a one-centimeter dorsal wedge of cortico-cancellous bone. The specimen was placed in the ABC jig and PA radiographs of each specimen were obtained and re-digitized at the proximal and distal edges of the osteotomy with corresponding global markers for motion transformations.

Augmented Fixation

Each fixator for each specimen was tested both with and without a dorsal transfixion K-wire. After the first fixator that had been applied had been tested following the osteotomy, a single 0.062-inch K-wire was used to augment fixation. The K-wire was drilled at a 45-degree angle in the sagittal plane from the dorsal lip of the distal radius, across the osteotomy site and through the volar cortex. A schematic diagram is provided in Figure 5. The K-wire augmented construct was then tested using the above protocol. The second fixator that was applied was tested with the K-wire construct first and then subsequently tested after it had been removed. The third external fixator that was applied was first tested without the K-wire augmentation and then with it. The fourth and final fixator was tested first with the K-wire and then without it. The testing of the fixators with and without the k-wire augmentation was done in this manner to minimize the number of times that the k-wire would have to be inserted and then removed. Additionally,

because the external fixators were tested in random order, this prevented all of the fixators from having one construct always tested before the other.

Data Analysis

Three-dimensional rotation and translation motions of the distal radial fragment were calculated in reference to the stationary proximal radius. The 3D Optotrak coordinates were converted to local reference coordinated by a computer algorithm that referenced the distal and proximal osteotomy edges on the previous AP radiographs. Range of motion was calculated in the flexion/extension plane and in the radial/ulnar plane. Additionally, rotational motion was calculated. Comparisons between fixators were made using a two-tailed paired Student's t-test. Comparisons of the constructs with k-wire augmentation against the same device without k-wire augmentation were performed using a one-tailed paired Student's t-test. A p-value of less than or equal to 0.05 was considered significant. All calculations were performed using Excel (Microsoft Inc.; Redmond, WA).

RESULTS

Motion was measured prior to osteotomy in all three planes for each specimen tested. Motion in all three planes was negligible and within the error of our measurement technique.

Flexion/Extension Motion

The average range of motion (ROM) for the four fixators without k-wire augmentation was 4.5° (±0.6°) and improved to 2.6° (±0.4°) with the addition of a single, dorsal transfixion wire. K-wire augmentation significantly improved stability in the Orthologic device ($p<0.002$), the Orthofix frame ($p<0.02$), and the AO fixator ($p<0.04$). The EBI fixator also showed a similar trend toward reducing motion, but the difference was not statistically significant ($p<0.07$). There were not any differences between the fixators prior to k-wire augmentation. With k-wire augmentation, the only significant difference was that the Orthofix was shown to have increased stability over the EBI ($p<0.01$). The flexion/extension ROM for each of the fixators, both with and without k-wire augmentation, is shown in Figure 6.

Radial/Ulnar Deviation Motion

Prior to k-wire augmentation, the fixators allowed an average radial/ulnar deviation ROM of 3.0° (±0.4°) which was reduced to 1.5° (±0.2°) with the addition of the k-wire. K-wire augmentation significantly reduced the ROM for the Orthologic device ($p<0.003$). There was a similar trend for the EBI ($p<0.11$) and AO ($p<0.10$) fixators, but neither was statistically significant. Comparing the fixators before k-wire augmentation, the only significant difference was the Orthofix providing greater stability than the Orthologic. However, there were not any significant differences among the

fixators with k-wire augmentation. The radial/ulnar deviation ROM for the each of the fixators, with and without k-wire augmentation, is shown in Figure 7.

Rotational Motion

The average rotational ROM of the distal radial fragment was 3.2° (±0.4°) prior to the addition of the transfixion k-wire, and was 1.8° (±0.3°) after k-wire augmentation. K-wire augmentation significantly improved stability in the EBI ($p<0.0.05$) and the AO ($p<0.04$). The reduction in ROM seem with Orthologic fixator approached statistical significance ($p<0.06$). The EBI was shown to be less stable than the Orthofix ($p<0.03$) prior to k-wire augmentation, and was less stable than the AO ($p<0.04$) and Orthofix ($p<0.008$) when the fixators were compared with the transfixion k-wire. The rotational ROM for each of the four fixators is shown in Figure 8.

DISCUSSION

Despite wide variations in mechanical properties of the four fixators tested, we demonstrated that there were minimal differences in fracture stability under physiologic loads. There is some evidence that the EBI fixator is relatively less stable, particularly in reducing rotational motion of the distal radial fragment. However, because many comparisons were performed, the differences noted may be somewhat spurious, although evidence for a difference between the EBI and the Orthofix frames is strengthened as the Orthofix had a reduced range of motion for both flexion/extension and rotational ranges of motion. This work corroborated our previous findings that augmentation of an external fixator with a single dorsal transfixion wire significantly improved fracture stability for extra-articular distal radius fractures.[27] Improvements in fracture stability were seen for each of the three ranges of motion that were measured: flexion/extension, radial/ulnar deviation, and rotational motion. Each fixator demonstrated a significant reduction in at least one of these three planes with the addition of the transfixion k-wire. K-wire augmentation significantly reduced flexion/extension motion of the distal radial fragment for the Orthologic, EBI, and Orthofix fixators. Significant reductions in radial/ulnar deviation were only observed for the Orthologic device. The EBI and AO fixators both showed a similar trend, but wide variations for the two fixators most likely prevented the differences from being statistically significant. K-wire augmentation significantly reduced the rotational motion of the distal radial fragment for both the EBI and AO fixators. Based on the results of the present study, it appears that stability of distal radius fracture fixation may be more dependent on means to augment fixation, such as the use of Kirschner wires, than on the strength of an external fixator itself.

Rigid fixation has been shown both clinically and histologically to enhance bone healing.[30] As discussed earlier, previous biomechanical studies compared external fixators using wooden dowels or acrylic bars and externally applied bending and compression loads.[19,32,33] These authors showed wide variation in fixator rigidity, and categorized the Orthofix fixator in a rigidity class far superior to the others tested. The authors concluded that the lightweight fixator designs should be reserved for "small to average patients," and a more rigid fixator used for more active patients. The testing forces, however, were not applied in physiologic fashion, and the authors conceded that the ideal rigidity of an external fixator is not known. In most instances, a fixator is designed to share load with the fracture site, and generally does not function to span a gap between two bone segments. Muscular forces during activities of daily living are not well understood, and a fixator is not designed to withstand externally applied anterior/posterior and lateral bending in most cases.

Clinical studies comparing fixators cite little difference in outcomes between designs. As Frykman noted, an ideal clinical study would be "based on a large well-controlled clinical trial in which outcomes of treatment with all of the devices ... could be carefully compared and evaluated." As discussed earlier, a few small clinical trials have been performed to compare a limited number of fixators. While the results of Foster and Kopta suggested greater rigidity of the Hoffman fixator compared to the Anderson device, the authors concluded that neither fixator yielded superior results with respect to patient satisfaction, pain, grip strength, resumption of pre-injury activity, or wrist or finger stiffness.[31] In Cooney's clinical comparison of four external fixators (Anderson, Ace-Colles, mini-Hoffman, and Hoffman C-series), he found that

each fixator yielded similar good-to-excellent results and patients showed equivalent ranges of motion. Additionally, there were not any differences in the types or numbers of complications. He concluded that clinical results appear to be independent of the external fixator used. The results of those limited clinical comparisons are consistent with the biomechanical results in this study in that neither supports a clinically significant difference in outcome between the many commercially available external fixators.

Factors that must be taken into account when considering outcomes of external fixation include the type and severity of the fracture, the mechanical strength and porosity of the patients' bone, postoperative rehabilitation protocol, and additional means to augment fracture stability. This study supports the concept of K-wire augmentation of an external fixator for an unstable distal radius fracture. Statistically significant reductions in the fracture fragment motion were seen for each of the four fixators evaluated in at least one of the three planes of motion. Additionally, several of the augmented constructs showed trends consistent with reduced fragment stability that were not statistically significance. This lack of significance can be attributed to wide variations in ROM of the distal fragment as well as the relatively small sample size of seven specimens.

The study was limited to an extra-articular distal radius fracture model, and thus cannot be directly extrapolated to apply to intra-articular fractures. This was done to eliminate several variables and to develop a reproducible model for testing many different fixator constructs which would not have been possible with an intra-articular osteotomy. Because the investigation was designed to study several different fixator and pin combinations, we

purposefully limited the fracture variables to a simple model to specifically examine the differences in fixation stability. One can surmise, however, that an indirect reduction of comminuted intra-articular fragments would not lead to improved fracture stability. In addition, because we studied only one percutaneous K-wire position for augmentation it is not possible to conclude that addition of a percutaneous K-wire in any other position would demonstrate comparable improvements in stability. The single dorsal transfixion pin has been previously demonstrated to show the greatest reduction in fragment motion in the flexion/extension plane,[27] and is likely attributed to its position in a plane normal to the axis of rotation for flexion/extension motion.

During this study, the maximal force across the wrist was 98N. Unfortunately, there has been no previous research to determine the exact muscular forces across the wrist during light activity. Prior biomechanical studies on cadaveric specimens with wrist fractures have used forces ranging from 88N to 135N.[35,36,37]Another study by Horri et al used 143N as their estimate of the load across the wrist while grasping a one-kilogram force.[38] Their estimate was based on the theoretic calculations of several authors, including Cooney[39] and Chao[40]. This study did not attempt to elucidate the forces across the wrist during light activity. However, because the forces used are in accordance with previous loads used, it is reasonable to expect that the results can be viewed in comparable fashion to the previous biomechanical work on external fixators. One final limitation of our study was the relatively small sample size as only seven cadaver specimens were used. Although the nature of the study allowed for paired comparisons, potentially clinically significant trends seen in reduced fracture fragment stability did not reach

statistical significance. Unfortunately, the sample size was limited by the number of available cadaver forearm specimens.

In summary, the purpose of our study was to use a physiologic testing model to compare four external fixators of widely divergent strength and design, and to study the effect of K-wire augmentation on fracture construct stability. The results of this study do not support a significant difference in external fixator stability, and show that augmentation with a dorsal transfixion K-wire appears to be an important mechanism of increasing stability of distal radius fractures, regardless of the fixator utilized. Future research in this area would benefit from increased sample size. More importantly though, research comparing external fixators would benefit from a large-scale, controlled, randomized clinical study. Ideally, this study would evaluate the many different external fixators with respect to both anatomical and functional outcomes.

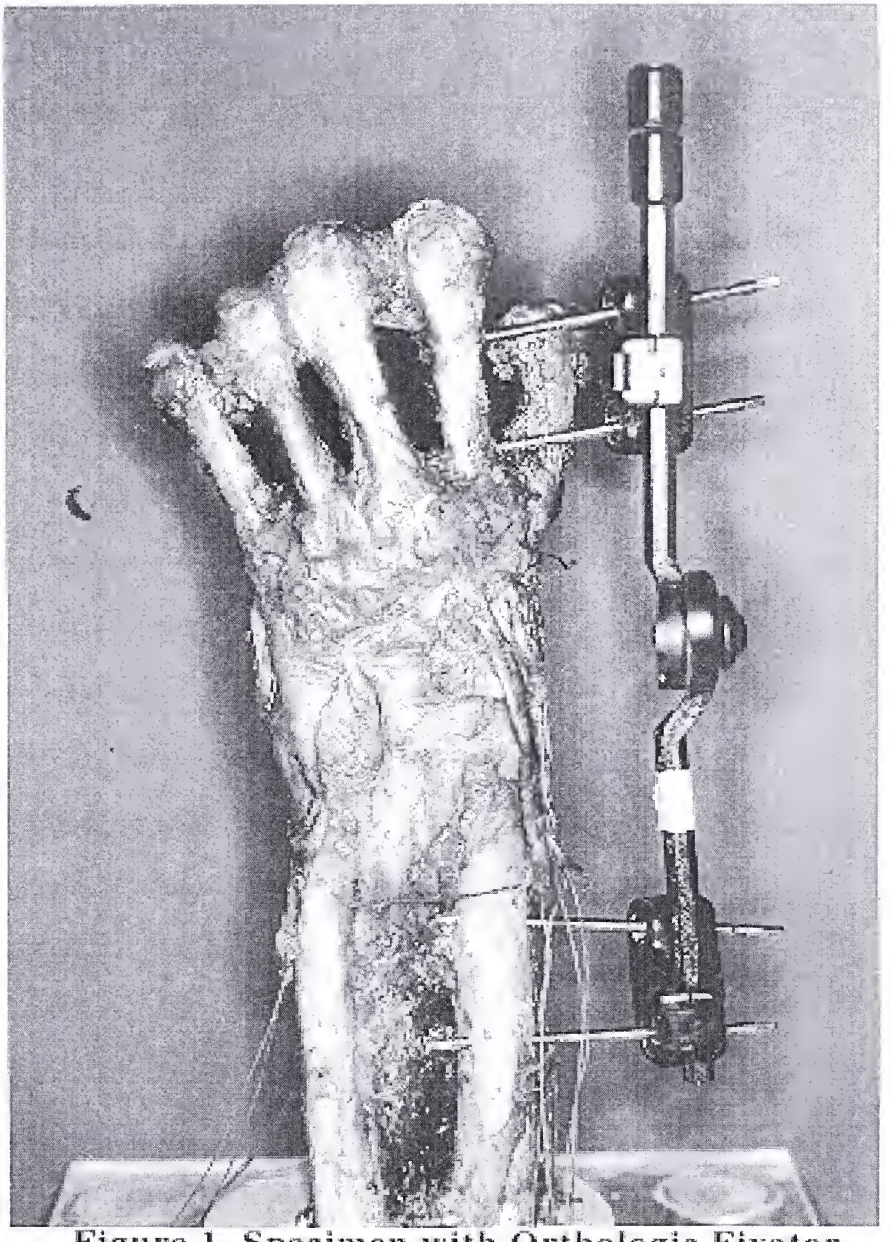


Figure 1. Specimen with Orthologic Fixator.

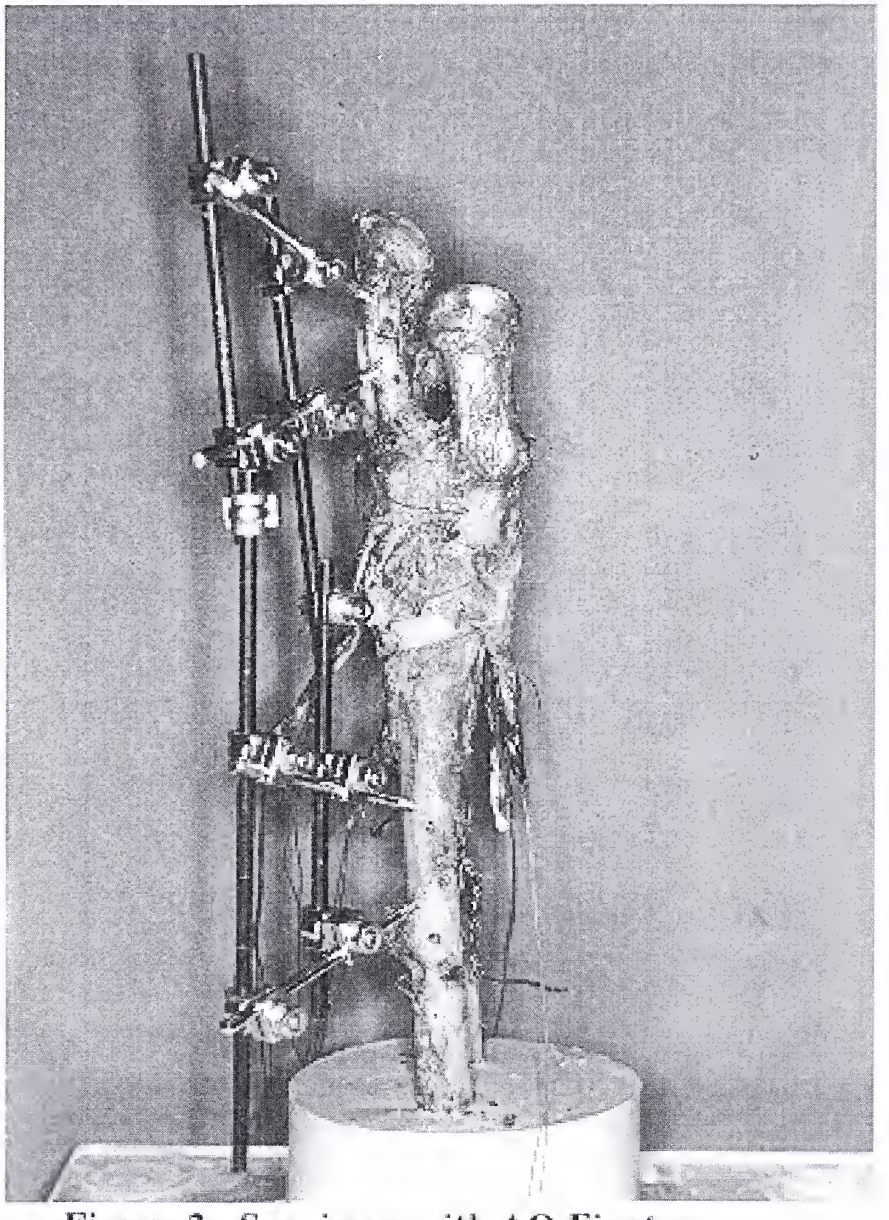


Figure 2. Specimen with AO Fixator.

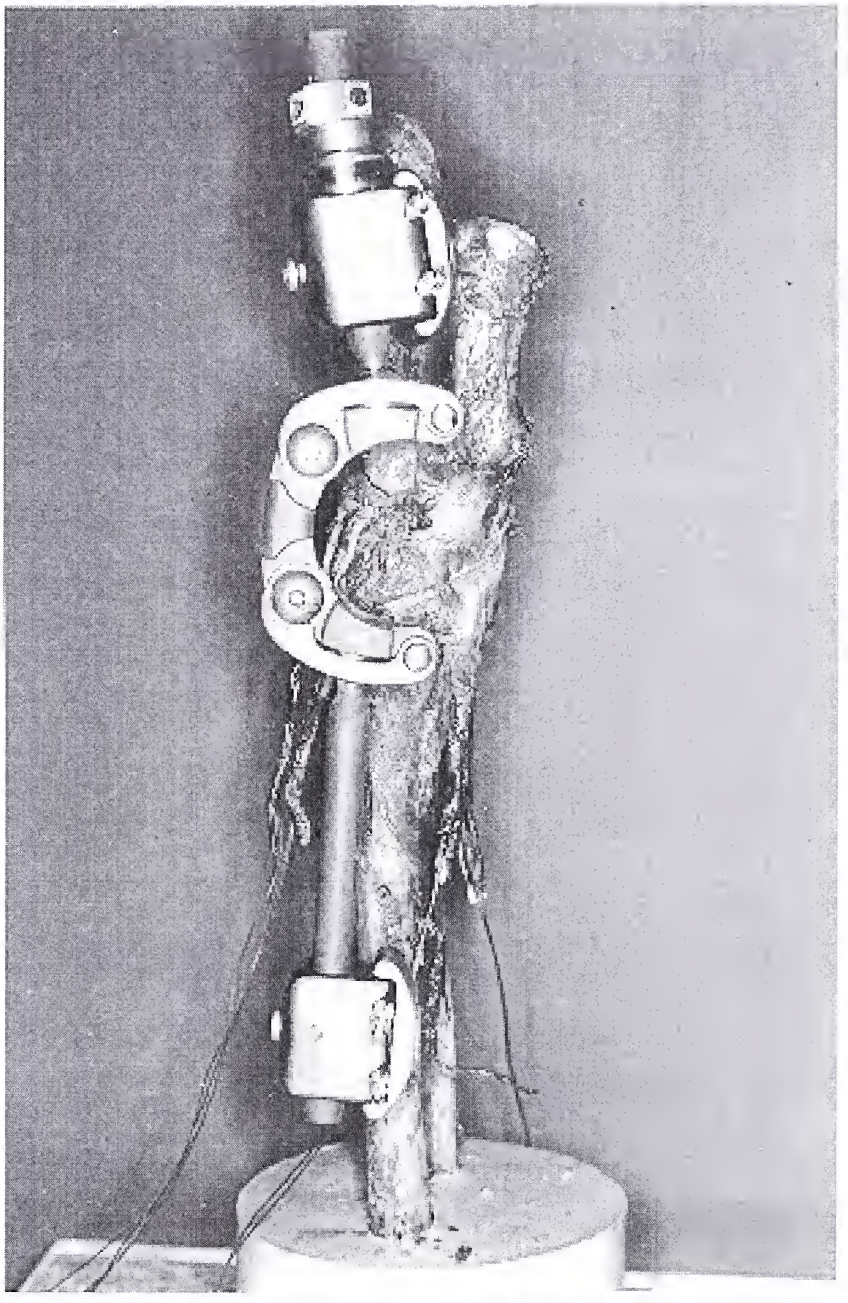


Figure 3. Specimen with EBI Fixator.

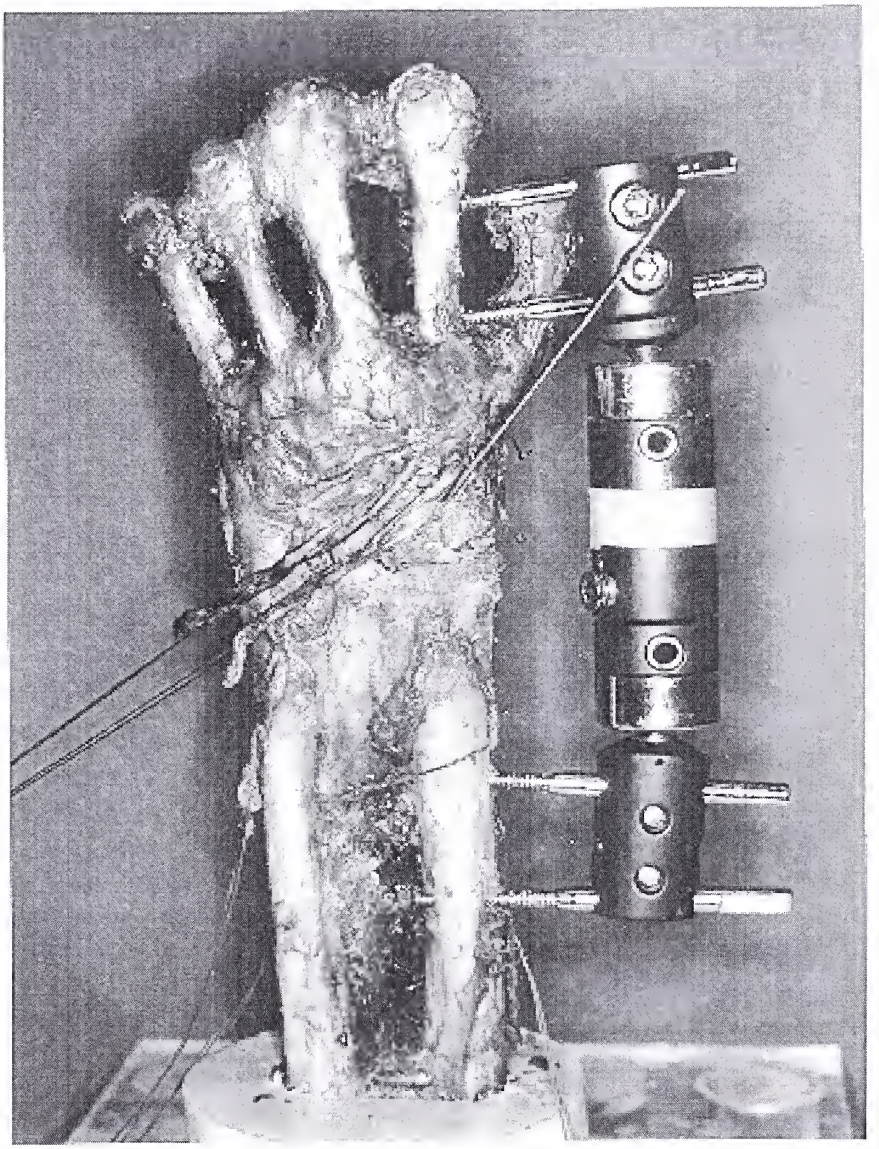


Figure 4. Specimen with Orthofix Fixator.

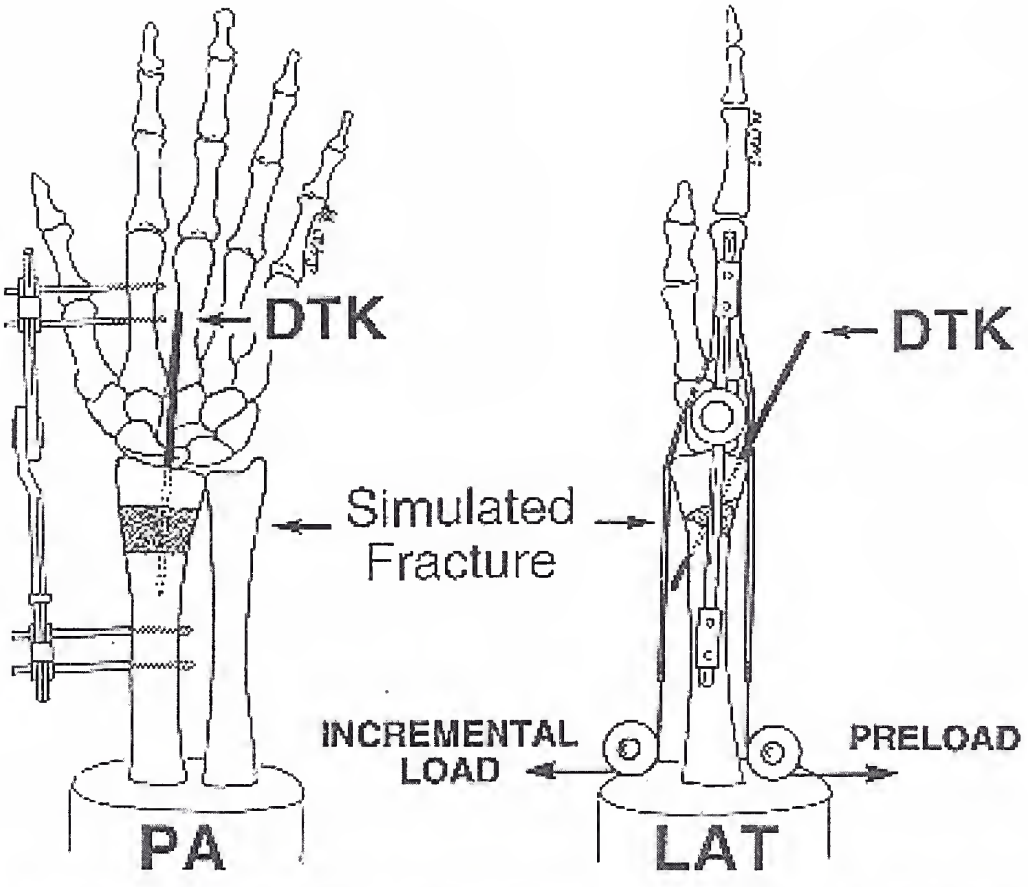
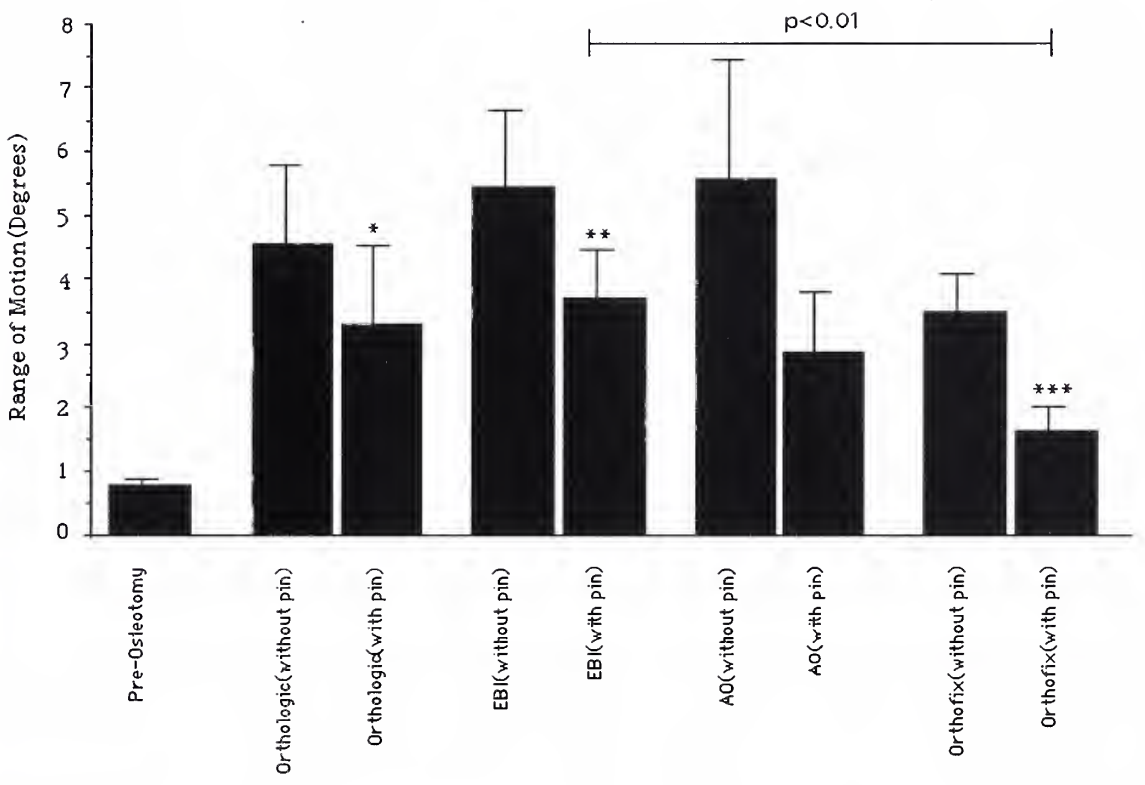
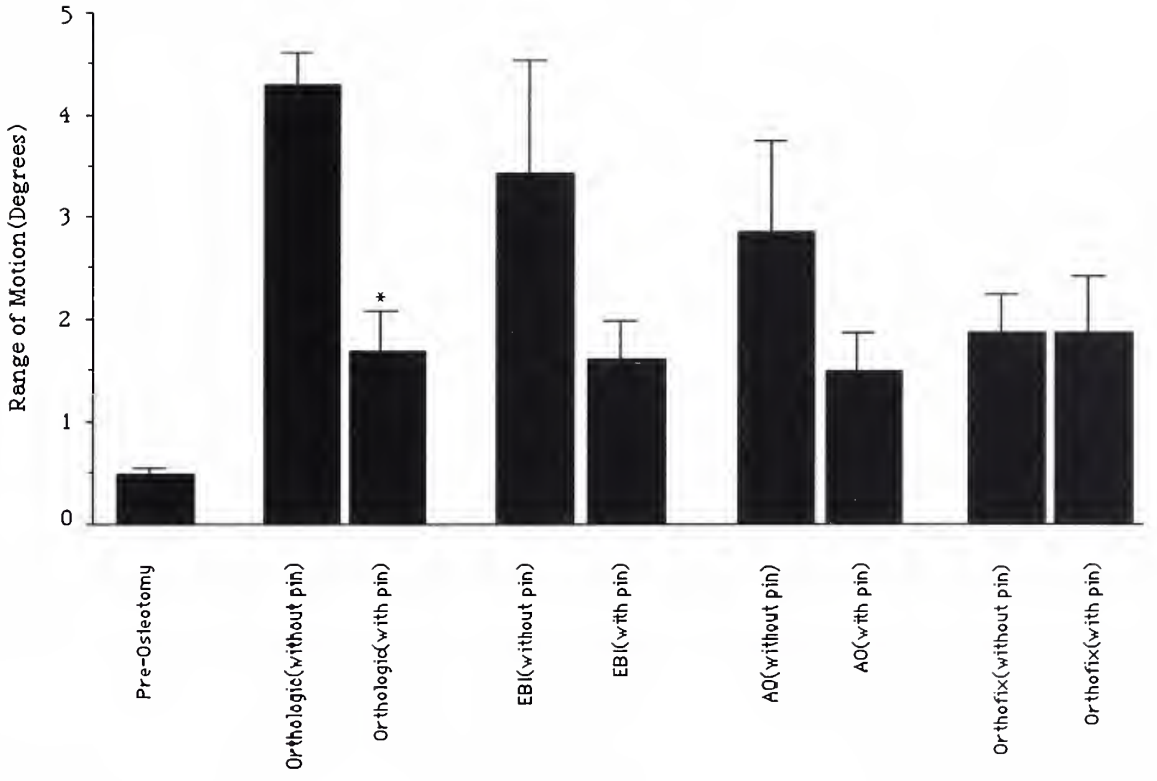


Figure 5. Schematic PA and Lateral view of the Dorsal Transfixion K-wire.



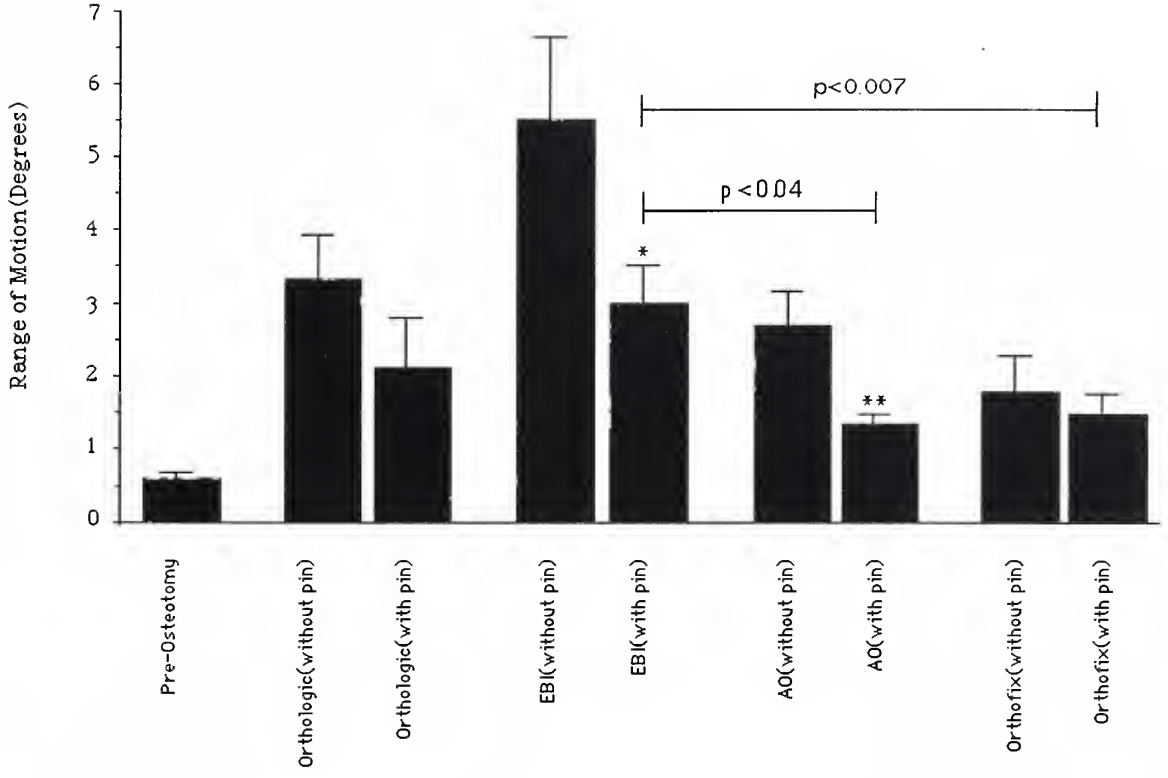
* p < 0.002
** p < 0.04
*** p < 0.02

Figure 6. Comparison of Range of Motion between the External Fixators in the Flexion/Extension Plane



* $p < 0.003$

Figure 7. Comparison of Range of Motion between the External Fixators in the Radial/Ulnar Plane



* $p < 0.05$

** $p < 0.04$

Figure 8. Comparison of Rotational Motion between the External Fixators

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